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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/570,937	07/17/2006	David Morton	478.1076	8966

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EXAMINER	
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/570,937	MORTON ET AL.	
	Examiner	Art Unit	
	Christopher R. Lea	1619	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 April 2009*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *23,24,31 and 38-64* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *23,24,31 and 38-64* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *08 March 2006* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/8/2006 & 6/23/2006*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

This application is a 371 (national stage application) of PCT/GB04/03935.

Claims 23, 24, 31, & 38-64 are pending. Claims 23, 24, 31, & 38-64 are under examination.

Election/Restrictions

1. Applicant's election without traverse of Group II, claims 23, 24, & 31 in the reply filed on April 6, 2009, is acknowledged. Applicant added claims 38-64 and these new claims will be included in the elected group for the purpose of examination. Applicant has canceled all claims to the non-elected species.

Priority

2. Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

3. The information disclosure statement(s) (IDS) submitted on March 8 and June 23, 2006, were filed before the mailing date of the first office action on the merits. The submission is in compliance with the provisions of 37 CFR 1.97 & 1.98. Accordingly, the information disclosure statement is being considered by the examiner.

4. The information disclosure statement filed May 15, 2006, fails to comply with 37 CFR 1.98(a)(1), which requires the following: (1) a list of all patents, publications,

applications, or other information submitted for consideration by the Office; (2) U.S. patents and U.S. patent application publications listed in a section separately from citations of other documents; (3) the application number of the application in which the information disclosure statement is being submitted on each page of the list; (4) a column that provides a blank space next to each document to be considered, for the examiner's initials; and (5) a heading that clearly indicates that the list is an information disclosure statement. The information disclosure statement has been placed in the application file, but the information referred to therein has not been considered.

Specification

5. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 23, 24, 31, & 38-64 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating premature ejaculation with clomipramine, does not reasonably provide enablement for treatment with all

antidepressants. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention commensurate in scope with these claims.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in *In re Wands,* 8 USPQ2d1400 (Fed. Cir. 1988). Among these factors are: 1) scope or breadth of the claims; 2) nature of the invention; 3) relative level of skill possessed by one of ordinary skill in the art; 4) state of, or the amount of knowledge in, the prior art; 5) level or degree of predictability, or a lack thereof, in the art; 6) amount of guidance or direction provided by the inventor; 7) presence or absence of working examples; and 8) quantity of experimentation required to make and use the claimed invention based upon the content of the supporting disclosure.

Scope or breadth of the claims

The claims are drawn to a method of treating premature ejaculation (PE) through the oral administration of an antidepressant. The claims encompass any antidepressant.

Nature of the Invention

The invention is a method of administering to the lungs an antidepressant to treat premature ejaculation.

Relative level of skill possessed by one of ordinary skill in the art

The relative level of skill possessed by one of ordinary skill in the art of medical research is relatively high, as a majority of lead investigators directing scientific research and development in this particular technological area possess an M.D. and/or

a Ph.D. in a scientific discipline such as organic synthetic chemistry, medicinal chemistry, biochemistry, pharmacology, biology or the like.

State of, or the amount of knowledge in, the prior art

Bolell (US PreGrant Publication 2002/0091129) teaches that around the time of the invention, no drugs had been approved for the treatment of premature ejaculation, but that a few antidepressants (namely the tricyclic clomipramine and the SSRIs sertraline, and paroxetine) had "off-label" use as such.

Level or degree of predictability, or lack there of, in the art

The pharmaceutical arts are inherently unpredictable. There is also unpredictability in the conventional prior art methods of premature ejaculation treatment; particularly, the rational development of new PE treatments is hampered by the poor understanding of its causative mechanisms in general.

Amount of guidance or direction provided by the inventor

The application lists over 100 antidepressant compounds by name (though there are possible dozens more unnamed) that may be used in the present invention; however, the applicant cites only two independent studies that treated PE with antidepressants. These two studies used clomipramine or clomipramine, paroxetine and sertraline. Additionally, the instant specification discloses that "The mechanisms by which the various antidepressants are thought to work vary considerably between the various types of antidepressants" (page 6, lines 14-16). Hence, there is no expectation that any given antidepressant would be effective to treat PE, based solely on the fact that it functions as an antidepressant.

Presence or absence of working examples

All of the working examples disclosed by applicant make use of clomipramine.

Quantity of experimentation required to make and use the invention

The experimentation would consist of picking an antidepressant, formulating it in an inhalable composition, administering it to a subject in need of treatment, and determining whether or not it was effective for treating PE. If unsuccessful, which is likely given the few that have shown effect and the relatively large number of antidepressants, the skilled artisan would be forced to select another antidepressant and repeat the unpredictable process again until successful. Therefore, it would require undue experimentation to use the invention in a manner commensurate in scope with the claims.

In conclusion, given the lack of working examples that incorporate an antidepressant other than clomipramine, the dearth of results for the treatment of PE by antidepressants save clomipramine, paroxetine, and sertraline, and the absence of an antidepressant being approved for the treatment of PE (at least at the time of the invention), the person of ordinary skill in the art would have to engage in an undue amount of experimentation to use the invention in a manner commensurate in scope with the claims.

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 31, 43, 58, 59, & 60 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The term "easily be tolerated" in claims 31 & 58 is a relative term which renders the claim indefinite. The term "easily be tolerated" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is unclear at what point a side effect is tolerated versus "easily" tolerated, particularly by the undisclosed "average recipient" as is claimed. As such, the metes and bounds of the claim are indeterminable, hence the claim is indefinite.

Claims 43, 59, & 60 recite the limitation "...less than about ..." which is indefinite. Either the limitation is "less than" or it is "about". "Less than" defines a static endpoint, "about" is dynamic about a point. Absent a definition of "about", the combination renders the metes and bounds of the claims indeterminable.

Claim 58 recites the limitation "the medicament" in line 2. There is insufficient antecedent basis for this limitation in the claim. The examiner will interpret "the medicament" as the "the composition" which does have antecedent basis in claim 23.

Claim Rejections - 35 USC § 102

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

11. Claims 23, 24, 31, 38, 43, 44, 58, 59, & 61-64 are rejected under 35 U.S.C. 102(b) as being anticipated by Tam et al. (US PreGrant Publication 2002/0161016).

Claim 23: Tam et al. disclose a composition containing clomipramine (an antidepressant) in a form for pulmonary administration (example 5, paragraphs 92 & 94). The composition is administered to a subject to treat premature ejaculation (PE) (paragraphs 105 & 106, and claims 1 & 21).

Claims 24, 31, & 58: As to the claimed side effect profile, where the claimed and prior art products are identical in structure or composition, or are produced by identical processes, a *prima facie* case of anticipation has been established. Further, The U.S. Patent Office is not equipped with analytical instruments to test prior art compositions for the infinite number of ways that a subsequent applicant may present previously unmeasured characteristics. When as here, the prior art appears to contain the exact same ingredients and applicant's own disclosure supports the suitability of the prior art composition as the inventive composition component, the burden is properly shifted to applicant to show otherwise. Absent evidence to the contrary, the prior art composition must possess the claimed side effect profile, since it is substantially identical to the claimed composition (See MPEP § 2112.01).

Claim 38: Tam et al. disclose clomipramine (example 5, paragraphs 92-95) which is a tricyclic antidepressant (paragraph 40).

Claims 43 & 59: Tam et al. disclose the composition (example 5) has an effective dose of 8.25-24.75 mg (2.5 g in 100mL, 0.33mL/compression, 1-3 compressions/dose, paragraphs 92-95).

Claims 44 & 61-64: As to the claimed onset of efficacy, where the claimed and prior art products are identical in structure or composition, or are produced by identical processes, a *prima facie* case of anticipation has been established. Further, The U.S. Patent Office is not equipped with analytical instruments to test prior art compositions for the infinite number of ways that a subsequent applicant may present previously unmeasured characteristics. When as here, the prior art appears to contain the exact same ingredients and applicant's own disclosure supports the suitability of the prior art composition as the inventive composition component, the burden is properly shifted to applicant to show otherwise. Absent evidence to the contrary, the prior art composition must possess the claimed onset of efficacy, since it is substantially identical to the claimed composition (See MPEP § 2112.01).

Claim Rejections - 35 USC § 103

12. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

13. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

14. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

15. Claims 23, 39-42, 45, & 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tam et al. (US PreGrant Publication 2002/0161016).

Applicant claims

Applicant claims a method for treating premature ejaculation through the pulmonary inhalation of an antidepressant.

Determination of the scope and content of the prior art (MPEP 2141.01)

Since claims 39-42, 45, & 60 ultimately depend from claim 23, rejection of claim 23 under 35 USC 103 is also appropriate.

Tam et al. teach, as a whole, administration of antidepressants to treat premature ejaculation.

Claim 23: Tam et al. teach a composition containing clomipramine (an antidepressant) in a form for pulmonary administration (example 5, paragraphs 92 & 94). The composition is administered to a subject to treat premature ejaculation (PE) (paragraphs 105 & 106, and claims 1 & 21).

Claim 39: Tam et al. teach that a single antidepressant or a combination of antidepressants can be administered in the composition (paragraph 44).

Claim 40: Tam et al. teach that other active agents (not antidepressants) can be administered in the composition (paragraphs 44-46). Tam et al. also teach that the other active agents will generally be one that is effective in treating PE (paragraph 44). Tam et al. specifically teach benzodiazepines as possible other active agents (paragraph 46).

Claim 45: Tam et al. teach that the composition for treating PE may be a dry powder (paragraph 74).

Claim 60: Tam et al. teach that the composition delivers 0.1-300 mg per dose (paragraph 78).

Ascertainment of the difference between the prior art and the claims (MPEP 2141.02)

The difference between the teachings of Tam et al. and the instant claims is that Tam et al. do not exemplify an embodiment that possesses the claimed limitations (two antidepressants, second active agent, or dry powder inhalation form).

Finding of *prima facie* obviousness
Rationale and Motivation (MPEP 2142-2143)

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to formulate a composition for treating PE with 2 antidepressants, a second active agent, or as a dry powder for inhalation as taught by Tam et al. and produce the instant invention. The skilled artisan would have been motivated to formulate the compositions because it is within purview of the skilled artisan to select a known material based on its suitability for its intended use. Reading a list and selecting a known compound to meet known requirements is no more ingenious than selecting the last piece to put in the last opening in a jig-saw puzzle (see MPEP § 2144.07).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in formulating a composition for treating PE with 2 antidepressants, a second active agent, or as a dry powder for inhalation as taught by Tam et al. and producing the claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

16. Claims 46-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tam et al. as applied to claim 45 above, and further in view of Staniforth et al. (US PreGrant Publication 2003/0162835).

Applicant claims

Applicant claims a method for treating premature ejaculation through the pulmonary inhalation of an antidepressant in the form of a dry powder.

Determination of the scope and content of the prior art (MPEP 2141.01)

Detailed discussion of the rejection of claim 45 and the teachings of Tam et al. appears above.

Ascertainment of the difference between the prior art and the claims (MPEP 2141.02)

The difference between the teachings of Tam et al. and the instant claims is that Tam et al. do not specifically teach the claimed size limitations, excipients, and carrier particles. This deficiency in Tam et al. is cured by the teachings of Staniforth et al.

Staniforth et al. teach, as a whole, a method for making particles suitable for use in inhalable pharmaceutical compositions. Staniforth et al. teach making composite excipient particles for use in formulations for the local administration of agents including antidepressants (paragraph 48).

Claims 46 & 47: Staniforth et al. teach that the composite excipient particles have a mass median aerodynamic diameter of not more than 10 μm advantageously and not more than 5 μm preferably (paragraph 51).

Claims 48 & 49: Staniforth et al. teach that 90% by weight of the composite excipient particles have a diameter of less than 10 μm advantageously and less than 5 μm preferably (paragraph 51).

Claims 50 & 53: Staniforth et al. teach that the composite excipient particles comprise an excipient and an additive material (paragraph 51).

Claim 51: Staniforth et al. teach that the optimum amount of additive material will depend on chemical nature of the additive material and excipient (paragraph 24). Further, Staniforth et al. teach that additive material is preferably 2-20% based on the total weight of the additive material and excipient (paragraph 24). Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation (MPEP § 2144.05).

Claim 52: Staniforth et al. teach that leucine, magnesium stearate, lecithin, and sodium stearyl fumarate may be additive materials (paragraphs 33-36).

Claim 54: Staniforth et al. teach the inclusion of carrier particles in the composition (paragraph 54) and that the particles are of the size between 20 and 250 μm preferably (paragraph 55).

Finding of *prima facie* obviousness
Rationale and Motivation (MPEP 2142-2143)

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to use the methods for making an inhalable pharmaceutical taught by Staniforth et al. to formulate a composition for use in the method taught by Tam et al. and produce the instant invention. The skilled artisan would have been motivated to combine the teaching of the references because it is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, namely for inhalation administration of an antidepressant, in order to form a third composition to be used for the very same purpose. The idea of combining them flows logically from their having been individually taught in the prior art (See In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) and MPEP § 2144.06).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in using the methods for making an inhalable pharmaceutical taught by Staniforth et al. to formulate a composition for use in the method taught by Tam et al. and producing the claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

17. Claims 55-57 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tam et al. as applied to claim 23 above, and further in view of Lewis et al. (US PreGrant Publication 2002/0025299).

Applicant claims

Applicant claims a method for treating premature ejaculation through the pulmonary inhalation of an antidepressant in a form useful in a pressurized metered dose inhaler.

Determination of the scope and content of the prior art (MPEP 2141.01)

Detailed discussion of the rejection of claim 23 and the teachings of Tam et al. appears above.

Claims 55-57: Tam et al. teach that the formulations for inhalation may be in the form of aqueous solutions and/or suspensions (paragraph 74).

Ascertainment of the difference between the prior art and the claims (MPEP 2141.02)

The difference between the teachings of Tam et al. and the instant claims is that Tam et al. do not teach using the composition in a pressurized metered dose inhaler. This deficiency in Tam et al. is cured by the teachings of Lewis et al.

Lewis et al. teach, as a whole, stable pharmaceutical compositions for administration in a pressurized metered dose inhaler. Lewis et al. teach that the compositions may be used to administer active agents besides those specifically disclosed (paragraph 24).

Claim 55: Lewis et al. teach a composition comprising a solution of active agent, co-solvent and propellant in a pMDI (paragraph 16).

Claim 56: Lewis et al. teach that formulations for use in a pMDI can be a suspension, though this has been problematic (paragraph 4)

Claim 57: Lewis et al. teach that the propellants for use in the composition are HFAs, specifically HFA 134a and HFA 227 (paragraph 8).

Finding of *prima facie* obviousness
Rationale and Motivation (MPEP 2142-2143)

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to use the composition useful as an inhalable pharmaceutical taught by Lewis et al. to formulate a composition for use in the method taught by Tam et al. and produce the instant invention. The skilled artisan would have been motivated to combine the teaching of the references because it is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, namely for inhalation administration of an active agent, in order to form a third composition to be used for the very same purpose. The idea of combining them flows logically from their having been individually taught in the prior art (See In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) and MPEP § 2144.06).

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in using the composition useful as an inhalable pharmaceutical taught by Lewis et al. to formulate a composition for use in the method taught by Tam et al. and producing the claimed invention. Therefore, the invention as a whole would have been *prima facie* obvious to one of

ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

In light of the forgoing discussion, one of ordinary skill in the art would have concluded that the subject matter defined by the instant claims would have been obvious within the meaning of 35 USC 103(a).

Conclusion

Claims 23, 24, 31, & 38-64 are rejected. No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher R. Lea whose telephone number is (571) 270-5870. The examiner can normally be reached on Mon-Thu 7:30-5:00 ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on (571)272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

CRL

/Johann R. Richter/

Supervisory Patent Examiner, Art Unit 1616